Dear Panel Physician:

On September 30, 1996, the United States Congress amended the Immigration and Nationality Act by revising the health-related grounds of inadmissibility. A new subsection, **PROOF OF VACCINATION REQUIREMENTS FOR IMMIGRANTS**, has been added and this new subsection requires any alien who seeks an immigrant visa to show proof of having received vaccination against certain vaccine-preventable diseases. Congress also amended the Act to allow the alien to apply for a waiver if : (1) the alien receives the vaccines that were initially missing, (2) the vaccine(s) would not be medically appropriate, or (3) compliance with the vaccination requirement would be contrary to the alien's religious beliefs or moral convictions. This new vaccination requirement applies to all immigrant visa applicants and must therefore be incorporated into the medical exam process. This new vaccination requirement has necessitated that instructions be developed so that panel physicians can include the new requirement as part of the medical examination. The instructions are based on recommendations made by the Advisory Committee on Immunization Practices (ACIP). The ACIP is an advisory committee to the United States Centers for Disease Control and Prevention (CDC) that makes general recommendations on immunization, including safe and effective immunization schedules. **These new immunization technical instructions shall apply to all medical examinations and are now in effect.**

Enclosed are the technical instructions and guidance for implementing the new vaccination requirements. These new instructions on immunization should be added to

the document Technical Instructions for Medical Examination of Aliens, June 1991, and be included in the medical examination of all applicants. It is anticipated that the Technical Instructions for Medical Examination of Aliens and The Medical Examination of Applicants for United States Visas Optional Form (OF-157), will be revised later this year to formally include these changes. Please note that panel physicians must give a **copy** of the supplemental form to OF-157 to all applicants for their personal records.

If you have any questions about the new immunization instructions, please write or contact me by fax at (404) 639-2599. Also, we would appreciate receiving any comments or suggestions you might have on the new vaccination requirements.

Thank you for including this new requirement in the medical examination process.

Sincerely yours,

Robert Wainwright, M.D.
Director
Division of Quarantine
National Center for Infectious Diseases

Enclosure

“ADDENDUM TO THE
TECHNICAL INSTRUCTION FOR
MEDICAL EXAMINATION OF ALIENS
JUNE 1991"

VACCINATION REQUIREMENTS FOR IMMIGRANT VISA APPLICANTS

April 1997

Background

These instructions and the accompanying tables are based on recommendations made by the Advisory Committee on Immunization Practices (ACIP), an advisory committee to the United States Centers for Disease Control and Prevention (CDC). The ACIP makes general recommendations on immunizations, including safe and effective immunization schedules, for individuals in the United States. These recommendations are directed to health care providers who are in clinical and preventive medicine and who usually provide continuing care, including immunizations. However, because vaccine circumstances and disease prevalence often differ in other countries, and since panel physicians normally see applicants only one time, ACIP’s recommendations are not completely translatable to practices that occur in foreign countries. As a result, these instructions and tables have been developed to provide guidance to panel physicians performing the medical examination. The following documents are provided to complement the written instructions below:

1. Table 1, Requirements for Routine Vaccination of Immigrants who are not Fully Vaccinated (or Have no Documentation) and Examined Overseas.
2. Table 2, *Major Contraindications to Vaccinations* Listed on Table 1.
3. Table 3, Vaccine Schedule for Routine Immunizations.

4. Chart 1, *Procedure for Determining Vaccination Status for Each Vaccine.*
5. Supplemental Form to OF-157.

Summary of Vaccination Requirements

Vaccinations Required

In general, an applicant must be administered a single dose of each vaccine listed in Table 1 as part of the medical examination.

Exceptions

1. If the applicant has already received a full series of a particular vaccine (or is immune to that disease), no further doses of that vaccine are required.

or

2. A dose of a particular vaccine is not required if a waiver is requested for that vaccine.

Waivers

Waivers are available under two circumstances:

1. Blanket waivers are available when receipt of a vaccine would not be medically appropriate (categories detailed below).
2. Individual waivers are available based on an individual's religious or moral objection to vaccination.

The consul officer will determine whether the applicant is eligible to receive a particular waiver.

Procedure for Determining Vaccination Status for Each Vaccine

1. **Written Vaccination History**

Obtain the applicant’s written record of vaccine history (applicant’s personal immunization record). Refer to Chart 1, *Procedure for Determining Vaccination Status for Each Vaccine.* Transfer the applicant’s vaccine history to the Vaccine History section of Supplemental Form to OF-157. Only those doses of vaccine that include date of receipt (month, day and year) are acceptable. Self-reported doses of vaccine without written documentation are not acceptable.

2. **Vaccination Series Complete Prior to Medical Examination**

Review the applicant's records to determine whether the applicant has received a complete series of each vaccine, or has written laboratory evidence of immunity to a disease for which vaccination is required. (Note the date of such laboratory evidence on the Supplemental Form to OF-157.)

A. Check "Yes" in the "Completed Series or Fully Immune" box, if complete for a particular vaccine, or if there is written *laboratory* evidence of immunity to one of the following four diseases: measles, mumps, rubella, or hepatitis B, *or, in the case of varicella (chickenpox), if there is a reliable history of the disease (verbal or written report of prior varicella [chicken pox] infection) or laboratory evidence of chickenpox immunity. Applicants who present evidence of immunity, or, in the case of varicella, a reliable history of the disease, require no further vaccination against those diseases. (The date of the laboratory test should be entered in the “Completed*

Series or Fully Immune" column of Supplemental Form to OF-157.)

B. If the vaccine history indicates that the applicant has received a complete series of **each** vaccine (or is immune to a disease for which a vaccine series has not been completed), check the box in section 3 for "Vaccine history complete for each vaccine, all requirements met."

3. **Vaccination Series Incomplete Prior to Medical Examination - Administration of Vaccines During Medical Examination or Application for Waiver(s)**

If the vaccine history shows that the applicant has not received a complete series of each vaccine (or no evidence of immunity), administer a single dose of each missing vaccine at the time of the medical examination,[1] note the date in the appropriate box in section 2, and check the box in section 3 for "Applicant may be eligible for blanket waiver(s) as indicated above," **except** do not administer a dose under the following circumstances that require application for a blanket "Not Medically Appropriate" waiver:

A. **Not Age Appropriate**

Table 1 shows which vaccines are indicated based on the age of the applicant at the time of the medical examination. For each vaccine for which administration is not age appropriate, check the "Not appropriate age" waiver box.

B. **Contraindication**

Table 2 shows the major contraindications to vaccination for each required vaccine. If the applicant has a contraindication, check the "Contraindication" waiver box for that vaccine.

C. **Insufficient Time Interval Between Doses**

Table 3 is the recommended routine schedule for vaccines administered in the United States. (You may also wish to consult your country's vaccination schedule, which may be available from your Ministry of Health or the vaccine manufacturer.) If a dose of a required vaccine has been administered prior to the medical examination, and the minimum interval for receipt of the next dose has not passed, check the "Insufficient time interval" waiver box for that vaccine.

D. **Seasonal Administration of Influenza Vaccine**

Influenza vaccine must be administered to age appropriate applicants only during the flu season. Check the "Not Flu Season" waiver box at other times of the year.

E. **Vaccine Unavailable in Country Where Medical Examination Performed**

When a required vaccine is not licensed and/or available in the country where the medical examination is performed, check the "Vaccine unavailable in country" waiver box for that vaccine.

F. **Religious or Moral Objection to Vaccination**

When an applicant objects to vaccination based on religious or moral grounds, check the box in section 3 for "Applicant will request an individual waiver based on religious or moral convictions."

4. **Vaccination Series Incomplete <u>After</u> Medical Examination - Waiver**

Completion of a vaccine series is not required to conclude the immigration medical examination, since such a requirement would require multiple visits to the panel physician and could lead to unnecessary delay in the immigration process. If administration of the single dose of a vaccine at the time of the medical examination **does not complete** the series for that vaccine (or the series requirements are not known), check the "Insufficient time interval" waiver box to indicate that additional doses would be required to complete the series for that vaccine (and check the box in section 3 for "Applicant may be eligible for blanket waiver(s) as indicated above.”)

5. **Vaccination Series Complete After Medical Examination**

If administration of the single dose of a vaccine at the time of the medical examination completes the series for that vaccine, check "Yes" in the “Completed Series or Fully Immune" box.

6. **Immunization Requirements Not Met - No Waiver Application**

If the applicant's vaccine history is incomplete, and the applicant refuses administration of a single dose of each missing

vaccine or is ineligible for a waiver, check the box in section 3 for "Applicant does not meet immunization requirements."

7. **Copy of Supplemental Form to OF-157**

A completed **copy** of Supplemental Form to OF-157 must be provided to each applicant. Note: Only the panel physician should complete the Supplemental Form to OF-157.

8. The panel physician should counsel all applicants who do not have a complete series for a vaccine to seek a private physician in the United States who can assist the applicant in becoming fully vaccinated.

[**footnote**] [1]The panel physician may refer the applicant to another health care provider to receive required vaccinations. In such a case, the panel physician should not complete the Supplemental Form to OF-157 until the applicant returns with a written record from the referral health care provider that notes the vaccines administered and the dates of administration.

Appendix A March 1998

AAddendum To The Technical Instructions For Medical Examination Of Aliens, June 1991", Vaccination Requirements For Immigrant Visa Applicants, April 1997

Questions and Answers on General Administration of Vaccines, General Contraindications and Precautions, and Specific Vaccines for Panel Physicians

The following general information is based on both U.S. and World Health Organization (WHO) experience with immunization programs. The information below reflects the recommendations of the U.S. Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the WHO=s worldwide Expanded Programme on Immunization (EPI).

The guidance on vaccines found in Section III is based on U.S. vaccines and standards but also reflects global vaccine information published by the WHO and United Nations Children=s Fund (UNICEF), in 1996, in the document entitled State of the World=s Vaccines and Immunizations.

Panel Physicians should use this information to inform potential vaccinees of all ages and their parents/caretakers regarding the benefits, contraindications and precautions related to vaccines and immunizations. Panel Physicians may choose to provide oral and, in some cases, written information about the benefits and precautions of vaccines and their administration.

I. General Administration

1. What can be considered proof of valid immunizations?

Written documentation is necessary and sufficient as evidence of prior immunization. In general, written immunization records may be considered valid if the vaccine, date of administration, interval between doses, and age of the patient at the time of vaccination would be appropriate for a comparable vaccine produced in the United States.

2. Is the storage and handling of vaccines important?

Yes. Failure to adhere to recommended specifications for storage and handling of vaccines can weaken these products or make them ineffective. Recommendations included in a product=s package inserts, including reconstitution of vaccines, should be followed closely to assure maximum potency of vaccines. Vaccine quality is the shared responsibility of all parties from the time the vaccine is manufactured until administration. Vaccines should be stored at recommended temperatures immediately upon receipt. Certain vaccines, such as oral polio vaccine(OPV) and varicella, are very sensitive to increased temperature. Other vaccines are sensitive to freezing, including diphtheria and tetanus toxoids combined and pertussis vaccine(DTP), diphtheria and tetanus toxoids combined and acellular pertussis vaccine(DtaP), diphtheria and tetanus toxoids for pediatric use (DT), tetanus and diphtheria toxoids for adult use (Td), inactivated poliovirus vaccine (IPV), Haemophilus influenzae type b conjugate vaccine (Hib), hepatitis B vaccine, pneumococcal vaccine, and influenza vaccine.

3. What if the required vaccine is not immediately available through the Panel Physician?

Normally the Panel Physician will refer the applicant to a facility where the vaccines are available. If the vaccine(s) are not available in-country, a medical waiver can be granted.

4. What if the Panel Physician does not know the age of a child?

Applicants seeking immunizations will do so as part of the required medical examination needed for a U.S. immigration visa. In the extremely rare event when neither the applicant=s caretaker nor the Panel Physician know the age of a child presenting for immunization, the Panel Physician should follow good medical practice. If the child does not present any

contraindications and has no proof of prior immunization, the child should receive the first dose of a series of vaccines appropriate for the estimated age of the child. Remaining doses can be administered after entry into the U.S.

5. Is there any risk if travel to U.S. is initiated shortly after receiving vaccinations?

There is normally no risk in initiating travel shortly (same day) after receiving one or more vaccinations. Even though there is normally no risk in travel shortly after vaccinations, Panel Physicians may advise when feasible that travel be delayed for a few days.

6. Can a child or person with poorly documented medical history receive vaccines?

Yes. Persons needing to receive vaccines will do so at the time of their medical examination for an immigration visa. Every effort should be made to vaccinate unless a contraindication exists, in which case a waiver may be necessary.

7. Is it an acceptable practice to administer several of the required vaccines simultaneously?

Studies and extensive clinical experience have strengthened the scientific basis for administering certain vaccines simultaneously. Many of the commonly used vaccines can safely and effectively be administered simultaneously (i.e., on the same day, <u>not</u> at the same anatomical site). The simultaneous administration of the most widely used live and inactivated vaccines, including varicella, has not resulted in impaired antibody responses or increased rates of adverse reactions.

8. If vaccines are administered simultaneously, how and where on the body should they be administered?

Vaccinators should be familiar with the structural anatomy of the area into which they are injecting vaccine. An individual decision on needle size and site of injection must be made for each person based on age, the volume of the material to be administered, the size of the muscle, and the depth below the muscle surface into which the material is to be injected. The deltoid is recommended for routine intramuscular vaccination among adults, particularly for hepatitis B vaccine.

With regards to an ideal distance between injection sites for multiple vaccinations in the same arm, the following is recommended: If more than one vaccine preparation is administered or if vaccine and an immune globulin preparation are administered simultaneously, it is preferable to administer each at a different anatomic site. It is also preferable to avoid administering two intramuscular injections in the same limb, especially if DTP is one of the products administered. However, if more than one injection must be administered in a single limb, the thigh is usually the preferred site because of the greater muscle mass; the injections should be sufficiently separated (i.e. 1-2 inches apart) so that any local reactions are unlikely to overlap.

9. What if a child vomits after taking OPV?

Infants may sometimes fail to swallow oral preparations (e.g., oral poliovirus vaccine (OPV)) after administration. If, in the judgment of the person administering the vaccine, a substantial amount of vaccine is spit out, regurgitated, or vomited shortly after administration (i.e., within 5-10 minutes), another dose can be administered at the same visit. If this repeat dose is not retained, neither dose should be counted, and the vaccine should be re-administered at the next visit.

II. General Information on Contraindications and Precautions

1. What are some examples of when vaccine(s) may not be medically appropriate?

Some examples of contraindications include:

I.

Neurologic or severe hypersensitivity reaction to a prior dose of DTP or DtaP is reason for a medical waiver.

Anaphylactic allergy to neomycin or streptomycin contained in polio, measles, mumps, and rubella vaccines is a reason for a medical waiver. Allergy to yeast in hepatitis B vaccine may also be a reason for a medical waiver.

Pregnancy. Combined Tetanus and diphtheria toxoid (Td) is the only vaccine routinely indicated for susceptible pregnant women. Polio, measles, mumps, rubella, and varicella vaccines should not be routinely administered to pregnant women.

Immunocompromised children. Special consideration needs to be given to immunocompromised children, such as those with congenital immunodeficiencies, HIV infection, and malignancy, or recipients of immunosuppressive therapy. Medical waivers for live virus vaccines, oral polio, measles, mumps, rubella, and varicella vaccine should be granted in these cases and vaccine not administered. Immunosuppressive therapies --including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids (used in greater than physiologic doses) - may reduce the immune response to vaccines. Although no specific studies with pertussis vaccine are available, if immunosuppressive therapy will be discontinued shortly, ***it is reasonable to defer vaccination until the patient has been off therapy for 1 month***. Otherwise the patient should be vaccinated while still on therapy. IPV (inactivated polio vaccine) may be used in these cases.

Malnutrition alone has not been shown to be a risk factor for adverse events and is not grounds for a waiver.

Fever *per se* is not a contraindication to immunization. For the child with an acute, febrile ($\geq$38°C) illness, guidelines for immunization are based on the physician's assessment of the child's illness and the specific vaccines the child is scheduled to receive. However, if fever or other manifestations suggest a moderate or serious illness, the child should not be vaccinated until recovered.

Moderate to severe vomiting may also be a reason to defer immunization.

2. When should persons with moderate or severe febrile illnesses be vaccinated?

These persons can be vaccinated as soon as they have recovered from the acute phase of the illness. This wait avoids superimposing adverse effects of vaccination on the underlying illness or mistakenly attributing a manifestation of the underlying illness to the vaccine.

3. What is the difference between a contraindication and a precaution?

A contraindication is a condition in a recipient which is <u>likely</u> to result in a life-threatening problem if the vaccine were given. A precaution is a condition in a recipient which <u>may</u> result in a life-threatening problem if the vaccine is administered, or a condition which could compromise the ability of the vaccine to produce immunity. When faced with the latter conditions (precautions), some providers may elect to administer vaccine if they believe that the benefits outweigh the risks for the patient. (For example, **caution** should be exercised in vaccinating a child with DTP who, within 48 hours of receipt of a prior dose of DTP, developed fever ≥40.5C (105F); had persistent, inconsolable crying for ≥3 hours; collapsed or developed a shock-like state; or had a seizure within 3 days of receiving the previous dose of DTP. These signs are not contraindications *per se*.)

The major **contraindications** include:

An immediate anaphylactic reaction

Encephalopathy (not due to another identifiable cause) <u>relating only to pertussis-containing vaccines</u>

Some **precautions** <u>(relating only to pertussis-containing vaccines)</u> include:

Fever ≥105F (≥40.5C) that is not attributed to another identifiable cause occurring within 48 hours after vaccination.

Collapse or shock-like state (i.e., a hypotonic-hyporesponsive episode) occurring with 48 hours after vaccination.

Persistent, inconsolable crying lasting ≥3 hours and occurring within 48 hours after vaccination.

Convulsions with or without fever occurring within 3 days after vaccination.

4. What are some of the safety considerations when administering vaccines?

Persons administering vaccines should take the necessary precautions to minimize risk for spreading disease. Hands should be washed before each new patient is seen. Syringes and needles used for injections must be sterile and preferably disposable to minimize the risk of contamination. ***A separate needle and syringe must be used for each injection***. Different vaccines should not be mixed in the same syringe unless specifically licensed for such use. Disposable needles and syringes should be discarded in labeled, puncture-proof containers to prevent inadvertent needle stick injury or reuse.

III. Information on Specific Vaccines

1. What are the different types of vaccines and what are the expected side effects from these vaccines?

There are two basic types of vaccines: live attenuated and inactivated. Live attenuated vaccines are produced by modifying a disease-producing (wild) virus or bacteria in a laboratory. The resulting vaccine organism retains the ability to replicate (grow) and produce immunity, but usually does not cause illness. Adverse events following live attenuated vaccines are similar to a mild form of the natural illness. For example, measles disease is characterized by rash and fever; the most common adverse events following measles vaccine are rash and fever. Adverse events following live vaccines occur after one incubation period of the vaccine virus (except allergic

reactions, which occur in minutes or hours). For example, the peak occurrence of fever and rash after measles vaccine is 7-10 days after vaccination. Live attenuated vaccines include oral polio vaccine, measles, mumps, rubella vaccines, and varicella vaccine.

Inactivated vaccines can be composed of either whole or partial (fraction or subunits) bacteria or viruses. Inactivated vaccines do not replicate, so adverse events are not similar to the natural disease. Since a large amount of killed bacteria or virus is given in the injection, the most common adverse events are local at the site of injection, such as pain, swelling, and redness. Fever may occur, often as a manifestation of inflammation at the site of injection. Local reactions to inactivated vaccines generally increase with increasing numbers of doses of the vaccine. Mild systemic symptoms can also occur. Adverse events from inactivated vaccines generally occur within 1-3 days of the dose of the vaccine (i.e., unrelated to the incubation period of the disease). Inactivated vaccines include Haemophilus influenzae type b vaccine, diphtheria and tetanus toxoids combined, pertussis (whole cell or acellular) vaccine, influenza vaccine, pneumococcal vaccine, and hepatitis B vaccine.

2. What are the benefits and risks associated with the *Haemophilus influenzae* type b Vaccine (Hib)?

About the Disease

To understand why the *Haemophilus influenzae* type b (Hib) vaccine is used, one must first understand the disease caused by the bacteria. Hib is a leading cause of acute lower respiratory tract infection among young children, especially in developing countries. While it is difficult to assess the global burden of Hib disease, it is estimated that over 500,000 children a year die from Hib pneumonia.

Hib is also one of the leading causes of non-epidemic meningitis, which can lead to brain damage and acquired deafness. It is estimated that more than 50,000 children die from Hib meningitis every year. The disease affects mainly children under five years (90% of all cases)-with peak incidence at 6-11 months.

About the Vaccine

Since 1990, four conjugate vaccines (vaccines which are made more potent by linking the cell wall of inactivated bacteria with a protein carrier) have been licensed for use in children from two months of age. In Finland and Iceland, where the vaccine was introduced in 1992, the incidence of the disease fell dramatically and it has now almost been eliminated. Most other industrialized countries are now seeing equally dramatic reduction in disease incidence.

What are the benefits of the Hib vaccine?

Vaccination is the best way to protect against Hib disease. Many children would develop severe Hib disease, with possible lifelong complications, without the vaccine.

What are the risks of the Hib vaccine?

Hib vaccine is one of the safest of all vaccines. As with any medicine, there is a very small risk that serious problems, even death, could occur after receiving a vaccination. However, the disease is much more likely to cause serious illness than the vaccine. Information based on adverse events following Hib vaccine licensed in the United States suggests that if adverse events occur, they usually start within 1 day of vaccination and may last 2-3 days. As expected following administration of an inactivated vaccine, they include redness, warmth, or swelling at the site of injection, fever, vomiting, diarrhea, or irritability.

3. What are the benefits and risks associated with the Polio vaccine?

About the Disease

To understand why the Polio vaccine is used, one must first understand the disease caused by this virus. Polio is a viral infection of the nervous system. It affects mostly children and can cause lifelong paralysis, respiratory distress, and sometimes death. Up to 95% of all polio infections are inapparent, but infected persons without symptoms shed virus in the stool and are able to transmit the virus to others. Although polio is incurable, it can be prevented by immunization.

About the Vaccine

Two vaccines are available: an inactivated injectable polio vaccine (IPV) and a live attenuated oral polio vaccine (OPV). Both vaccines are highly effective against all three serotypes of poliovirus, but there are significant differences in the way each vaccine works.

The oral polio vaccine is the vaccine of choice for use in the EPI. It is cheaper and easier to administer than the injectable vaccine. It also multiplies and induces immunity in the gut, the key site where wild poliovirus multiplies. Although OPV is safe and effective, in about two in every 5 million doses of the vaccine the live attenuated virus can cause paralysis, either in the immunized child or in a close contact.

Inactivated polio vaccine provides individual protection against polio paralysis, but it induces only very low immunity in the gut. Because of this, IPV cannot prevent the spread of wild poliovirus and cannot be used to eradicate polio in communities. However, IPV does not carry the risk of paralysis associated with OPV.

What are the benefits of the Polio vaccine?
Polio vaccine prevents polio. Before polio vaccine, hundreds of thousands of children acquired polio each year.

OPV: No injection. OPV provides individual protection and increases the protection for communities from polio outbreaks.

IPV: IPV provides individual protection from polio. It can be given to immunocompromised persons or to persons living in a household with immunocompromised persons. It does not cause paralysis.

What are the risks of the Polio vaccine?
OPV: In the United States, for example, where wild poliovirus has already been eradicated, the only source of the disease is now OPV. Every year 5-10 people become paralyzed following immunization with OPV - half of them recently immunized children and the rest non-immunized or partially immunized contacts. In response to mounting public concern, the US Advisory Committee on Immunization Practices decided in June 1995 to draw up new guidelines on polio immunization. In October 1995 the Committee

recommended the introduction of a combined IPV/OPV schedule in the United States - an initial two doses of IPV to be followed by two doses of OPV. The US Advisory Committee on Immunization Practices has emphasized that the IPV/OPV schedule applies only to the United States and have strongly endorsed WHO:s global eradication strategy. OPV cannot be given to immunocompromised persons or persons living in households with immunocompromised persons.

IPV: Mild soreness at the site of injection can occur.

4. What are the benefits and risks associated with the vaccines for Measles, Mumps, and Rubella (Measles or MR or MMR)?

About the Disease

To understand why the vaccines for measles, mumps, and rubella are used, one must first understand the diseases caused by these viruses.

1. Measles

Measles remains one of the major childhood killers, accounting for more child deaths than from all the other vaccine-preventable diseases combined. WHO estimates that about 40 million cases of measles occur each year but less than 5% are ever reported. The disease thrives in cities, especially in deprived urban areas where overcrowding, poor sanitation, and pockets of low immunization ensure the continued circulation of measles and other diseases.

Ninety-eight percent of the measles deaths occur in developing countries. Globally, the disease accounts for over 10% of deaths among children under five years and 50% under one year old. Measles can lead to lifelong disabilities, including brain damage, blindness, and deafness, especially in developing countries. Other complications include pneumonia, diarrhea, ear infections, and seizures.

2. Mumps

Mumps infection can cause fever, headache, lymphadenopathy, aseptic meningitis, deafness, orchitis, and oophoritis. Infrequently, pancreatitis may occur.

3. Rubella

Rubella (German measles) is a mild rash disease that affects mostly children. But if the disease is contracted by a woman during the first three months of pregnancy, the consequences for the developing fetus can be devastating. There is a 50% increase in spontaneous abortions. In up to 70% of cases, the baby is born with permanent disabilities, including blindness, deafness, brain damage, and heart defects. In developing countries, it is estimated that a quarter of a million babies are born with congenital rubella syndrome (CRS) annually. In an epidemic year, there is likely to be a tenfold increase in the incidence of CRS in individual countries.

About the Vaccine

Measles, mumps, and rubella vaccines are live attenuated viral vaccines.

A live attenuated rubella vaccine has been available since 1969. It is widely used in the industrialized world, although immunization schedules vary from one country to another. The vaccine is available as a single vaccine, in combination with measles vaccine (MR), or as a measles, mumps, and rubella combined vaccine (MMR).

What are the benefits of the vaccines for Measles, Mumps, and Rubella?

Vaccination is the best way to protect against measles, mumps, rubella and the complications from those diseases, including congenital rubella syndrome.

What are the risks of the vaccines for Measles, Mumps, and Rubella?

The adverse events following measles, mumps, rubella vaccine(s) represent replication of the virus(es) with subsequent mild illness. Allergic reactions would occur within minutes to hours following the vaccine administration. Soon after the vaccination, there may be soreness, redness, or swelling at the injection site. One to two weeks after the vaccination, there may be rash, fever, lymphadenopathy, or infrequently, a seizure.

Adverse events related to the measles component of the vaccine occur 5-12 days post-vaccination. The most common adverse events are fever and rash. Information from Sweden and Finland indicates that a decrease in the platelet count

(thrombocytopenia) may occur once in 30,000 to 40,000 doses of vaccine. Thrombocytopenia is usually not clinically apparent, although a few cases of thrombocytopenic purpura have been reported. Parotitis and fever have been reported rarely following mumps vaccine. In countries that use the Urabe strain of mumps vaccine virus, there is a slight risk of aseptic meningitis (one per several thousand doses). One to three weeks following the vaccination, there may be arthralgia or arthritis in one or more joints, lasting up to 3 days. This is believed to be the result of the rubella component of the vaccine. The joint complaints are more frequent in post-pubertal women.

5. What are the benefits and risks associated with the Diphtheria, Tetanus, and Pertussis Vaccines

About the Disease

To understand why the vaccines for diphtheria, tetanus, and pertussis are used, one must first understand the diseases caused by these bacteria.

1. Diphtheria

Diphtheria is an infectious disease caused by the bacteria (*Corynebacterium diphtheriae*) and is spread by coughing and sneezing or through contact with skin infections. It can affect the tonsils, upper respiratory tract and the heart. Although the disease can be treated with diphtheria antitoxin and antibiotics, even with appropriate treatment up to 10% of cases are fatal. Serious complications from the spread of diphtheria can occur, involving the heart (myocarditis) and central nervous system to various organs.

Diphtheria was a dreaded childhood illness in the pre-vaccine era and is re-emerging today in epidemics involving mainly adults and non-immunized children. Over time, with consistently high levels of immunization coverage in children under one, vaccine-induced immunity wanes and groups of non-immune individuals build up, creating the ideal conditions to seed an epidemic.

2. Tetanus

Tetanus is an acute, often fatal, disease caused by a toxin produced by the bacteria *Clostridium tetani*. It is characterized by generalized increased rigidity and convulsive spasms of skeletal muscles. The muscle stiffness

usually involves the jaw (lockjaw) and neck first, and later becomes generalized.

3. Pertussis

Pertussis (whooping cough) is an infectious disease caused by the bacteria *Bordetella pertussis.* In 1994 there were an estimated 40 million cases of pertussis worldwide and 360,000 deaths. Every year nearly 5 million children suffer from bronchopneumonia as a result of pertussis infection, while 50,000 children develop long-term neurological complications, including permanent brain damage. In developing countries the death rate can exceed 15% but is usually not so high. In the industrialized countries it is much lower, with 4 deaths out of every 10,000 infected children.

About the Vaccine

What are the benefits of the vaccines for Diphtheria, Tetanus, and Pertussis?

Vaccination is the most effective method of preventing these diseases and their serious complications, including death. Because it is not possible to eradicate the organism that causes tetanus, vaccination is the only method to prevent the disease.

What are the risks of the vaccines for Diphtheria, Tetanus, and Pertussis?
As with most inactivated vaccines, local reactions, such as pain, redness, and swelling at the injection site, are the most common adverse events observed. Fever and mild systemic reactions also occur frequently, usually starting within several hours of vaccination and lasting up to 1 to 2 days. Arthus-type hypersensitivity reactions, characterized by severe local reactions, may occur, particularly in persons who have had multiple prior boosters. These reactions are a result of high circulating levels of diphtheria antitoxin. Rarely, severe systemic reactions such as generalized urticaria, anaphylaxis, or neurologic complications have been reported.

Other reactions that can occur after pertussis vaccine are prolonged or unusual crying, high fever, seizure, and a

shock-collapse reaction (infant becomes pale, limp, and less alert). No long-term consequences of these reactions have been found. Very rarely, some children may have prolonged seizure activity or encephalopathy following the vaccine.

6. What are the benefits and risks associated with the Hepatitis B vaccine?

About the Disease

To understand why the vaccine for hepatitis B is used, one must first understand the disease and disease complications caused by the virus. More than 2 billion people today have at some time in their lives been infected with the hepatitis B virus (HBV). Of these, about 350 million remain chronically infected (carriers), developing cirrhosis of the liver, or liver cancer. Carriers are able to transmit the disease for many years. Every year there are over 4 million acute clinical cases of hepatitis B and approximately one million deaths. Primary liver cancer caused by hepatitis B is now one of the principal causes of cancer death in many parts of Africa, Asia, and the Pacific Basin.

Globally, child-to-child and mother-to-child transmission accounts for the majority of infections and carriers. Young children rarely develop acute clinical disease, but approximately 25% of children infected under the age of seven become carriers. No more than 10% of older children and adults become carriers. However, about 40% of older children and adults who are infected develop acute clinical hepatitis B with jaundice. The disease can also be transmitted through the use of unsterile needles or other medical equipment and through cultural practices which involve skin piercing.

In areas where there is low incidence of the disease (Western Europe, North America, much of Latin America, and Australia) mother-to-child and child-to-child transmission is less common. Most infections occur in adults through sexual activity, needle sharing among injecting drug users, and less frequently, among medical workers exposed to blood products.

About the Vaccine

There are two types of hepatitis B vaccines. The first vaccine to be developed has been available since 1981 and is

an inactivated vaccine derived from the plasma of HBV-positive donors. It has an outstanding record of safety and effectiveness and has been used to immunize more than 200 million people. The second vaccine, available since 1986, is a genetically engineered recombinant vaccine. It is equally safe and effective as the plasma-derived alternative.

What are the benefits of the Hepatitis B vaccine?
Vaccination is the most effective way to prevent hepatitis B infection and the serious complications and sequelae.

What are the risks of the Hepatitis B vaccine?
The most frequent adverse events following hepatitis B vaccine are pain at the site of injection and mild to moderate fever. Fatigue, headache, and irritability have also been reported. Serious allergic reactions have been reported rarely.

7. What are the benefits and risks associated with the Varicella vaccine?

About the Disease
To understand why the varicella vaccine is used, one must first understand the disease and disease complications caused by the virus. Chickenpox is a common childhood disease affecting millions of children a year. Although the disease is usually mild in otherwise healthy young children, it can be serious when contracted by older children or adults. It causes a rash, itching, malaise, and fever. It can lead to pneumonia, brain damage, or death. Persons who have had chickenpox can develop herpes zoster (shingles) later in life.

About the Vaccine
The chickenpox vaccine is a live attenuated vaccine. It was licensed for use in the United States in March 1995.

What are the benefits of the Varicella vaccine?
Varicella vaccine is the most effective way to prevent chickenpox and its complications. Persons who develop chickenpox after receiving the vaccine develop a milder case. Herpes zoster has been reported to occur 4-5 times less often following the vaccine than following the natural disease.

What are the risks of the Varicella vaccine?
Local reactions such as soreness, redness, or swelling at the site of injection may occur. A mild rash and fever can also occur approximately 2 weeks after the vaccination. Rarely, febrile seizures have been reported.

8. What are the benefits and risks associated with the Influenza vaccine?

About the Disease
To understand why the influenza vaccine is used, one must first understand the disease caused by the influenza virus. Influenza is a highly infectious viral illness. Influenza disease is characterized by the abrupt onset of fever, muscle aches, sore throat, and nonproductive cough. The symptoms usually last from 2 to 3 days. The most frequent complication of influenza is pneumonia, usually secondary bacterial pneumonia. Primary influenza viral pneumonia is an uncommon complication, but has a high fatality rate. Other complications of influenza include myocarditis, worsening of chronic pulmonary diseases, and death.

About the Vaccine

The Influenza vaccine that is used in most countries is composed of inactivated influenza virus. Because it is an inactivated vaccine, it cannot cause the flu.

What are the benefits of the Influenza vaccine?
The vaccine is effective in preventing disease in up to 90% of health young adults (US data). Although the vaccine is only 30%-40% effective in preventing disease in frail elderly persons, it is 50%-60% effective in preventing hospitalization in the elderly, and 80% effective in preventing death (US data).

What are the risks of the Influzenza vaccine?
Local reactions (soreness, erythema, and induration at the injection site) are the most common adverse events following influenza vaccination. These reactions usually last one to two days. Mild systemic symptoms, such as fever, chills, fatigue, and muscle aches are reported in <1% of vaccine recipients (US data). These reactions begin 6-12 hours after vaccination and last for 1 or 2 days. They occur most often

in persons with no prior exposure to the influenza virus or vaccine. Rare allergic reactions have occurred, and they likely are as a result of residual egg protein in the vaccine. Unlike the 1976 swine influenza vaccine, subsequent vaccines prepared from other virus strains have not been clearly associated with an increased risk of Guillain-Barre syndrome. Information from studies conducted since 1976 (US data) suggests that if an increased risk does exist, it is lower for persons aged ≥65 years than for those 18-64 years of age. The slight increase could be due to factors other than vaccine.

9. What are the benefits and risks associated with the vaccine for Pneumococcal Disease?

About the Disease

To understand why the pneumococcal vaccine is used, one must first understand the disease caused by the bacteria. Every year in developing countries, more than a million children under five years die from pneumonia caused by *Streptococcus pneumoniae*. This form of bacterial pneumonia is the biggest killer among the acute respiratory infections, which together claim the lives of over four million children a year in the developing world. *S. pneumoniae* is also responsible for pneumococcal meningitis, which has a fatality rate approximately as high as other forms of meningitis, and it often leads to hearing loss or brain damage in children who survive.

While early treatment with antibiotics saves many lives, there is increasing evidence that the misuse of antibiotics has led to the appearance of drug-resistant strains of the bacteria in many countries.

About the Vaccine

The pneumococcal vaccine is composed of purified preparations of pneumococcal cell wall. One of the major problems in developing a successful vaccine against *S. pneumoniae* is the large number of different serotypes involved. More than 83 serotypes of the bacterium are known to cause disease, about 10 of these account for up to 70% of disease in young children. The frequency of the serotypes can vary from year to year, from one age group to another, and from geographical area to area. Pneumococcal vaccines

are available which protect against 23 of the known serotypes. But these are not effective in children under two years, the age at which children are most vulnerable to the disease.

What are the benefits of the Pneumococcal vaccine?
The pneumococcal vaccine is 60%-70% effective in preventing invasive disease.

What are the risks of the Pneumococcal vaccine?
About half of those who are given pneumococcal vaccine have very mild side effects, such as redness and pain at the injection site. Infrequently, some persons may develop fever, muscle aches, and severe local reactions. Rarely, severe allergic reactions have been reported.

SUPPLEMENTAL FORM TO OF-157

Visa Applicant's Documentation of Immunization
To be completed by panel physician only

1. Applicant Identifying Information

_____ Date of Birth_____
(Family) (Personal) (Middle) (Month, Day, Year)

____Male____Female Passport #_____ Country_____

2. Immunization Record

Vaccine History Transferred from a Written Record					Vaccine Given	Completed series or Fully immune (Check if YES or write date of lab test if immune)	Waiver(s) to be Requested				
							Blanket				
							Not Medically Appropriate				
Vaccine	Date Rec'd Mo/Day/Yr	Date Rec'd Mo/Day/Yr	Date Rec'd Mo/Day/Yr	Date Rec'd Mo/Day/Yr	Date given by Panel Phy. Mo/Day/Yr		Not appropriate age	Contra-indication	Vaccine unavailable in country	Insufficient time interval	Not fall (flu) season
DT/DTP											////////
Td											////////
Polio (OPV/IPV)											////////
Measles (or MR or MMR)											////////
Mumps (or MMR)											////////
Rubella (or MR or MMR)											////////
Hib											////////
Hepatitis B											////////
Varicella											////////
Pneumococcal											////////
Influenza											

3. Results

☐ Applicant may be eligible for blanket waiver(s) as indicated above.

☐ Applicant will request an individual waiver based on religious or moral convictions.

☐ Vaccine history complete for each vaccine, all requirements met.

☐ Applicant does not meet immunization requirements.

4. Panel Physician's Identifying Information

Panel Physician's Name_____ Date_____
(print or type)

Panel Physician's Signature_____

**The following is cover letter dated March 9, 1998 which was sent to Panel Physicians indicating changes made to "Addendum to Technical Instructions for Medical Examination of Aliens, June 1991," Vaccination Requirements For Immigrant Visa Applicants, April 1997. These changes have been incorporated in the attached preceding copy of the addendum to the technical instructions.

Dear Panel Physician:

On April 11, 1997, the Centers for Disease Control and Prevention (CDC) distributed the technical instructions and guidance for implementing the new vaccination requirements for immigrants. In our cover letter to panel physicians, we asked that you provide us with any comments you may have after implementing the new instructions for vaccination requirements. We received a number of comments from panel physicians, and we have made appropriate changes based on those comments. Please substitute the enclosed pages in your technical instructions for vaccination requirements.

Pages Enclosed

Page 3, 5, Table 3 and addition of Appendix A.

Pages Superseded

Page 3, 5, Table 3 and addition of Appendix A.

Background

On page 3, Paragraph A has been modified to include varicella (chicken pox) and allows for a reliable history of the disease.

Paragraph A has been modified to read as follows: (changes noted in italics.)

A. Check "Yes" in the "Completed Series or Fully Immune" box, if complete for a particular vaccine, or if there is written *laboratory* evidence of immunity to one of the following four diseases: measles, mumps, rubella, or hepatitis B, *or, in the case of varicella (chickenpox), if there is a reliable history of the disease (verbal or written report of prior varicella [chicken pox] infection) or laboratory evidence of chickenpox immunity. Applicants who present evidence of immunity, or, in the case of varicella, a reliable history of the disease, require no*

further vaccination against those diseases. (The date of the laboratory test should be entered in the "Completed

Series or Fully Immune" column of Supplemental Form to OF-157.)

On page 5, in Paragraph D, the word "fall" has been deleted to clarify that the influenza vaccine should only be administered during the flu season in the country where the medical examination is being performed.

Table 3 has been modified to include additional vaccine schedule information for the following vaccines: Tetanus and Diphtheria Toxoids combined and Pertussis Vaccine (DTP), Tetanus and Diphtheria Toxoids Combined (Td), Measles Vaccine, and Varicella Vaccine. Also, reference to DtaP (Diphtheria and Tetanus toxoids and acellular pertussis vaccine) has been added to Table 3.

Appendix A should be added after page 6. Appendix A is entitled **"Questions and Answers on General Administration of Vaccines, General Contraindications and Precautions, and Specific Vaccines for Panel Physicians."** The appendix provides the panel physician with pertinent questions and answers concerning general administration of vaccines, general information on contraindications and precautions as well as information on specific vaccines.

We also want to inform you that on November 12, 1997, an immunization requirements exemption was signed into law which exempts immediate relative orphans who are 10 years of age or younger from the vaccination requirements. Therefore, these children will not have to meet the vaccination requirements at the time of the medical examination.

Lastly, the technical instructions in their entirety, including this revision, are now available at our internet address on the world wide web server at http://www.cdc.gov/ncidod/dq/technica.htm. Files are in Adobe Acrobat format.

Thank you for your assistance.

Sincerely yours,

Robert Wainwright, M.D.
Director

Division of Quarantine
National Center for Infectious Diseases

Enclosures